PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	06 JUN 2005

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
1662.004WO1	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US03/40806	19 December 2003 (19.12.2003)	20 December 2002 (20.12.2002)

Applicant

NATIONAL INSTITUTES OF HEALTH

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Dr. Kailash C. Srivastava F. Rebuds for
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Form PCT/IPEA/416 (July 1992)

P416

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1662.004WO1	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/40806	International filing date *(day/month/year)* 19 December 2003 (19.12.2003)	Priority date *(day/month/year)* 20 December 2002 (20.12.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/04; C12N 1/00, 1/20, 1/36, 1/38, 13/00; G01N 33/536, 33/539, 33/566 and US Cl.: 435/34, 173.4, 243, 244, 245, 253.6; 436/501, 536, 539		
Applicant NATIONAL INSTITUTES OF HEALTH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☒ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
20 July 2004 (20.07.2004)	18 May 2005 (18.05.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Dr. Kailash C. Srivastava Telephone No. (571)272-1600

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.
PCT/US03/40806

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-35 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages 36-41, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1-4, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.
PCT/US03/40806

II. Priority

1. ☐ This report has been established as if no priority has been claimed due to the failure to furnish within the prescribed time limit the requested:

   ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).

2. ☐ This report has been established as if no priority has been claimed due to the fact that the priority claim has been found invalid (Rule 64.1).

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:
Applicants Claim to priority for U.S. Provisional Serial Number 60/435,639 filed 20 December 2002 is acknowledged.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.
PCT/US03/40806

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-61	YES
	Claims NONE	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-61	NO
Industrial Applicability (IA)	Claims 1-61	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-61 lack an inventive step under PCT article 33 (3) as being obvious over Feldsine et al. (U.S. Patent 6,379,918) in view of Bochner (U.S. Patent 6,136,554). Feldsine et al. teach a culture medium among tryp soy broth (i.e., TSB), SOB, NZCYM, brain heart infusion, nutrient broth among others to selectively isolate/ detect presence of Salmonella or entero-hemorrhagenic Escherichia coli in presence of other pathogenic bacteria. (Abstract, Column 3, Lines 52-65; Column 4, Lines 21-24). Feldsine et al. further teach adding specific selection components (e.g., phage or chromogens) to selectively isolate enteropathogenic organisms (e.g., Escherichia coli and Salmonella) from environmental, water and body fluid samples (Column 9, Lines 4-8 and Lines 40-45). Feldsine et al., however, do not explicitly elaborate on each and every component of each of selective culture media, an antibiotic supplemented culture media or media comprising specific chromogens or selective agents (e.g., tellurite, tetrathionate, sorbitol, other organic and inorganic salts) to specifically isolate Salmonella species and Escherichia coli 0157:H7 isolates. Bochner teaches specific components for a variety of culture media that comprise specific selective agent, i.e., tellurite, selenite, sorbitol, tetrathionate, antimicrobials or antibiotics (e.g., novobiocin or propionic acid or other microorganism retarding agents, oxgall) and inorganic and organic (e.g., proteose peptone, yeast extract, enzymes or enzyme detecting substrates) components (Abstract; Column 19, Lines8-64; Column 22, Lines 22-59; Column 224, Lines 8-42; Column 25, Lines 5-1; Lines 54-67, Column 31, Lines 28-39; Tables 11-4 and Column 53, Lines 1-32).

Thus, at the time, the claimed invention was made, it would have been obvious to an artisan of ordinary skill in the art to combine the teachings from Feldsine et al. with those of Bochner to selectively isolate Salmonella, Entero-hemorrhoagenic Escherichia coli or Escherichia coli O157: H7from food, environmental, body fluid or water samples comprising a variety of competitive microorganisms on a variety of selective culture media. Said culture media are comprised of a number of organic or inorganic nutrients, selective agents described above, wherein selective agents are inorganic salts, bile salts, chromogens, phages and antimicrobial agents/antibiotics constituted in a selective culture medium such as nutrient broth or supplemented to known commercially available selective media (e.g., brain heart infusion, TSB, SOB, NZCYM). In view of the fact that the applicant's invention also recites a composition comprising the same ingredients as those taught in Examiner cited prior art references, applicant's invention is obvious over the teachings of Examiner-cited prior art references and therefore dies not have an inventive step.

Claims 1-61 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.